Evaluating Pharmaceutical Wastes

This fact sheet, which is provided by the Kentucky Division of Compliance Assistance (DCA) in partnership with the Division of Waste Management (DWM), is intended to help health care providers correctly identify waste pharmaceuticals that are hazardous waste.

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This information has been adapted from documents provided by the Minnesota Pollution Control Agency.

Environmental Concerns

Health care facilities can generate hazardous waste from many sources, including disposal of pharmaceuticals. Hazardous waste, if managed improperly, may harm human health and the environment.

This fact sheet offers general guidance to help health care providers **evaluate pharmaceutical wastes** (determine whether they meet the definition of hazardous waste). This fact sheet is not a substitute for the governing regulations. For help identifying and evaluating non-pharmaceutical wastes, please contact contact the Division of Waste Management or e-mail envhelp@ky.gov. For information on proper disposal of hazardous wastes, please see the publications listed at

www.waste.ky.gov

What is a "pharmaceutical waste"?

Pharmaceutical waste may include, but is not limited to

- expired drugs.
- patients' personal medications.
- waste materials containing excess drugs (syringes, IV bags, tubing, vials, etc.).
- open drugs that cannot be used.
- containers that held drugs.
- drugs that are intended to be discarded.
- contaminated garments, absorbents and spill cleanup material, except for materials with only trace contamination.

Each pharmaceutical waste must be evaluated to determine whether it is hazardous. Pharmaceuticals that are hazardous waste must be disposed of as hazardous waste. Hazardous waste disposal is not the same as medical or solid waste disposal.

Must all discarded pharmaceutical materials be evaluated?

All discarded pharmaceutical materials must be evaluated except for these two situations:

1. Pharmaceuticals that can be reused and may be returned to the manufacturer or a reverse distributor are not considered waste and, therefore, are not subject to evaluation. Pharmaceuticals managed this way must not be mixed together, leaking, partially used liquids or pastes, inherently waste-like or display any other characteristics that would reasonably preclude their beneficial reuse as products.

2. Medical supplies and containers that are "RCRA empty" (empty as defined by RCRA – the Resource Conservation and Recovery Act) are not subject to evaluation. "RCRA empty" means that **all** of the following criteria are met:

- all material that can be removed by normal means has been removed **and**
- less than 3 percent by weight of the total container capacity remains **and**
- supplies and containers do not contain residue from a P-listed hazardous waste. P-listed waste is defined in 401 KAR 31:040. A simplified P-list can be found at

  http://www.dca.ky.gov/complianceassistance/resources/Waste+Resources.htm

Waste that meets the definition of "RCRA empty" should be disposed of as infectious or solid waste – whichever is appropriate.

Pharmaceutical Hazardous Wastes Regulated by Other Rules

Sometimes pharmaceutical wastes are regulated by both hazardous waste rules and other rules. For example,

- pharmaceutical hazardous wastes may also be regulated by the Kentucky Division of Waste Management (DWM) and Occupational Safety and Health Administration (OSHA) as infectious waste, such as a syringe containing a pharmaceutical with a mercury preservative.
- pharmaceutical hazardous wastes may also be regulated by the U.S. Drug Enforcement Agency (DEA) as a controlled substance, such as waste phentermine.
- pharmaceutical hazardous wastes may also be regulated by the U.S. Nuclear Regulatory Commission (USNRC) as a radioactive waste, such as waste liquid scintillation cocktail.

When evaluating a waste, be sure to consider all regulations – not just hazardous waste – that affect how waste must be managed and disposed. Remember, the guidance offered in this fact sheet only considers hazardous waste regulations.

Evaluation Tool

Use the attached flowchart to determine whether a pharmaceutical waste is hazardous. Also determine whether the waste is regulated under other rules as discussed above. Before beginning, make a list of all pharmaceuticals used in the health care facility. Follow the flowchart for **each** pharmaceutical. **All pharmaceutical wastes in the facility must be evaluated.**

More Information and Contacts

Waste Management – The DWM and DCA have staff available to answer waste management questions (see contact list). Contact DCA or the nearest regional office for more information about and assistance with managing hazardous waste.

Sewering – Do not discharge pharmaceutical wastes to an individual sewage treatment system (septic tank). Get approval from the wastewater treatment plant operator before discharging any pharmaceutical wastes into a wastewater system. Be sure to notify the operator of all ingredients (actives and all others) in any wastes to be sewered. Check for state and local requirements regarding the sewering of pharmaceuticals.

Fact Sheets – The Kentucky DWM has fact sheets that provide detailed information about Kentucky's hazardous waste requirements. Find them on the DWM Web site at

http://www.waste.ky.gov/factsheets/.

Regulatory Consensus on Health Care Issues-For guidance on regualtory issues and interpretations on a variety of health care topics, please see the fact sheet located at DWM and DCA web sites.

For direct links to the Code of Federal Regulations (CFR) regarding hazardous waste definitions, please see

http://www.waste.ky.gov/branches/hw/Hazardous+Waste+Regulations+with+links.htm

Field Operations Hazardous Waste Offices

Central Office	502-564-6716
Bowling Green	270-746-7475
Columbia	270-384-4735
Florence	859-525-4923
Frankfort	502-564-3358
Hazard	606-435-6022
London	606-330-2080
Louisville	502-429-7120
Madisonville	270-824-7532
Morehead	606-784-6634
Paducah	270-898-8468

Web site
http://www.waste.ky.gov/branches/fo/

Kentucky Division of Waste Management
Frankfort 502-564-6716
Web site
http://www.waste.ky.gov

Kentucky Division of Compliance Assistance
Toll free 800-926-8111
Web site
http://www.dca.ky.gov

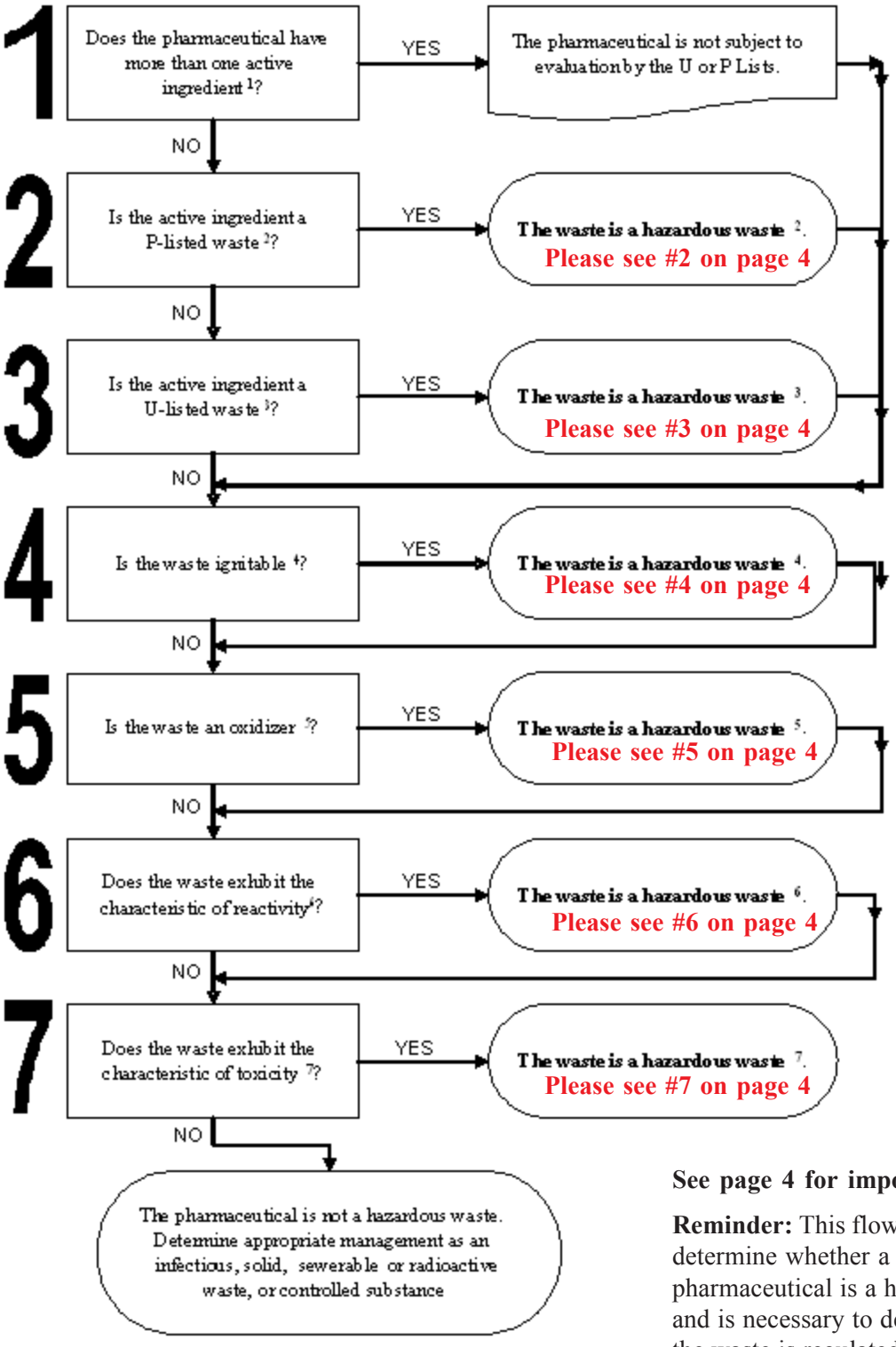
Kentucky Pollution Prevention Center
Toll free 800-334-8635
Web site
http://www.kppc.org

Hospitals for a Healthy Environment
http://www.h2e-online.org/

Evaluation Tool

Remember, every pharmaceutical waste in the facility must be evaluated!

The explanations given on page 4 corresponding to each step contain important information that will help ensure correct evaluation and proper management.



Reminder: Any rinseate or residual from containers that contained a hazardous waste must be collected and managed as hazardous waste.

See page 4 for important notes!

Reminder: This flowchart only helps determine whether a waste pharmaceutical is a hazardous waste and is necessary to determine whether the waste is regulated under other rules in addition to the hazardous waste rules.

Flowchart Notes

1 The **active ingredient** is the component that performs the function of the product. Fillers, solvents, carriers, propellants, preservatives, etc., are not active ingredients.

2 P-Listed drugs are defined in 401 KAR 31:040. A simplified P-List can be found at

http://www.dca.ky.gov/complianceassistance/resources/Waste+Resources.htm

Per **Kentucky State Regulation 401KAR 31:010, Section 3**, pharmaceuticals placed on the P and U Lists solely for the characteristic of ignitability, corrosivity or reactivity that do not exhibit that characteristic at the point they become waste are not considered P- or U-Listed hazardous wastes. However, they must still be evaluated for all other hazardous waste criteria. Characteristic hazardous waste is defined in 401 KAR 31:030. These characteristics can be found at

http://www.waste.ky.gov/branches/hw/Hazardous+Waste+Regulations+with+links.htm

Dispose of an unused or unusable pharmaceutical (e.g. open medication, residual IV solution) P- and U-Listed wastes as hazardous wastes. Manage contaminated equipment, garments, absorbents and spill clean-up materials as hazardous wastes. Used pharmaceuticals (e.g. removed nicotine patches) are not considered P- or U-Listed wastes; however, they must be evaluated for all other hazardous waste criteria. Waste residue remaining in a used syringe is considered a used pharmaceutical.

Containers that held a P-Listed pharmaceutical waste are also hazardous unless they are triple-rinsed; **the rinseate is also hazardous**. Rinsing is not recommended for containers that are also infectious waste; manage them as a hazardous waste.

3 U-Listed drugs are defined in 401 KAR 31:040. A simplified U List can be found at

http://www.dca.ky.gov/complianceassistance/resources/Waste+Resources.htm

Manage an unused or unusable pharmaceutical (e.g. open medication, residual IV solution) listed on the U List as a hazardous waste.*

Manage contaminated equipment, absorbents, other materials and spill materials associated with the U List as hazardous waste.

4 **Ignitable** wastes have a flash point of less than 140°F or meet one of the other criteria for ignitability given at 401 KAR 31:030. Manage a waste pharmaceutical that is ignitable as a hazardous waste.* Also, manage moist, contaminated materials as a hazardous waste that exhibit this characteristic.* Do not air dry absorbents. *Do not air dry absorbents as this is considered treatment onsite requiring permitting by DWM.*

5 A waste exhibits **corrosivity** (401 KAR 31:030) if it has either of the following properties:

1. It is aqueous and has a Ph of less than 2 or greater than or equal to 12.5.

2. It is a liquid and corrodes steel at a rate greater than 6.35 mm per year.

Manage pharmaceuticals meeting the definition of corrosives as a hazardous waste.* Also, manage overtly contaminated absorbents and materials and spill material as hazardous waste that exhibit the characteristic.*

6 **Reactivity** is a characteristic regulated in Kentucky. Reactivity is defined in 401 KAR 31:030.

http://www.waste.ky.gov/branches/hw/Hazardous+Waste+Regulations+with+links.htm

Determine the reactivity threshold concentration of the pharmaceutical as a waste. When the concentration of the waste pharmaceutical is at or greater than the reactivity threshold concentration, manage the waste as a hazardous waste.* Also manage contaminated materials that exhibit reactivity as hazardous waste.*

7 A **toxic** waste contains one or more contaminants (such as mercury) at or above maximum allowable concentrations. For a complete list of toxic contaminants, see

http://www.lrc.ky.gov/kar/401/031/030.htm

Manage waste pharmaceuticals that exhibit the toxicity characteristic as a hazardous waste.* Also manage contaminated materials that exhibit the toxic characteristic as hazardous waste.* *Be sure any in-house testing is done in accordance with proper methodology and equipment is capable of meeting regulatory detection limits.*

***Managing Waste Pharmaceuticals Waste -**

http://www.h2e-online.org/docs h2epharmablueprint41506.pdf